K130222

Traditional 510(k) Submission

Change in Straumann Dental Implant Indications for Use

APR 2 9 2013

5. 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Contact Person:	Jennifer M. Jackson, MS	or	Christopher Klaczyk
Phone Number:	1-978-747-2509		1-978-747-2575
Fax Number:	1-978-747-0023		1-978-747-0023

Date of Submission: 28-Jan-2013

5.1 Name of the Device

Trade Name: Straumann® Dental Implant System
SLActive and Roxolid Product Families

Common Name: Dental Implants

Classification Name: Implant, Endosseous, Root-form

Regulation Number: §872.3640

5.2 Predicate Device(s)

K033922, Modification to ITI Dental Implant System
K033984, ITI Dental Implant System
K053088, SLActive Implants
K062129, P.004 Implants
K081419, Modified Dental Implant
K083550, Modified Dental Implant
K111357, Narrow Neck CrossFit (NNC) Ø3.3 mm Dental Implant System
K121131, Straumann Bone Level Ø4.1 mm and Ø4.8 mm Regular Connection (RC) Roxolid Dental Implants
K122855, Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Roxolid Dental Implants
K123784, Straumann Dental Implant System – SLA, SLActive and Roxolid Product Families

5.3 Device Description

The subject devices of the Straumann® Dental Implant System includes the following:
SLActive® and Roxolid®, Standard, Ø3.3 RN, 8, 10, 12, 14 & 16 mm
SLActive® and Roxolid®, Standard, Ø4.1 RN, 6, 8, 10, 12, 14 & 16 mm
SLActive® and Roxolid®, Standard, Ø4.8 RN, 6, 8, 10, 12 & 14 mm
SLActive® and Roxolid®, Standard, Ø4.8 WN, 6, 8, 10 & 12 mm
SLActive® and Roxolid®, Standard Plus, Ø3.3 RN, 8, 10, 12 & 14 mm
SLActive® and Roxolid®, Standard Plus, Ø4.1 RN and Ø4.8 RN, 6, 8, 10, 12 & 14 mm
SLActive® and Roxolid®, Standard Plus, Ø4.8 WN, 6, 8, 10, & 12 mm
Roxolid®, Standard Plus, Ø4.8 WN, 14 mm
SLActive® and Roxolid®, Tapered Effect, Ø3.3 RN and Ø4.1 RN, 8, 10, 12 & 14 mm
SLActive® and Roxolid®, Tapered Effect, Ø4.8 WN, 10, 12 & 14 mm
SLActive® and Roxolid®, Bone Level, Ø3.3 NC, Ø4.1 RC, and Ø4.8 RC, 8, 10, 12 & 14 mm

5.4 Indications For Use / Intended Use

Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

5.5 Technological Characteristics

The subject devices are identical to the corresponding Straumann predicate devices as far as design, materials, surface treatments, fundamental operating principles, and sterilization processes and procedures. The change proposed in this premarket notification modifies the Indications for Use for the SLActive® and Roxolid® dental implants.

There are no changes to or new surgical instruments or secondary components being introduced as a result of the proposed change.

5.6 Performance Testing

The bench and animal performance testing previously submitted in support of the referenced Straumann predicate devices were conducted according to the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"* and continues to be representative of the performance of the subject devices.

A review and summarization of the clinical literature associated with the use of two immediately loaded dental implants in the treatment of fully edentulous patients. The available data indicate that the use of two dental implants to treat fully edentulous patients is common; the evidence supports that performance of two immediately loaded dental implants is equivalent to the use of a greater number of implants for this indication. We also provide

consensus statements from the American Dental Association, the McGill Consensus and the York Consensus indicating that two implant restoration of fully edentulous mandibles should be the treatment of choice. This literature strongly supports the elimination of the limitation requiring the use of at least four dental implants for the treatment of the fully edentulous patient when the implants are to be immediately loaded.

5.7 Conclusion

The documentation submitted in this premarket notification supports the proposed modification to the Indications for Use of the SLActive® and Roxolid® dental implants. The subject devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

Ms. Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager
Straumann USA, Limited Liability Company
60 Minuteman Road
ANDOVER MA 01810

Re: K130222
Trade/Device Name: Straumann® Dental Implant System
SLActive and Roxolid Product Families
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 28, 2013
Received: January 29, 2013

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130222

Device Name: Straumann® Dental Implant System
SLActive and Roxolid Product Families

Indications for Use:

Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879
Date: 2013.04.29 09:55:02 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130222